JUL - 3 2000

K000586

SECTION E: 510(k) SUMMARY

This summary of safety and effectiveness information is submitted in compliance with 21CFR807.92.

January 24, 2000

Submitter Information:
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268

Contact Person: Margo Enright
Phone Number: 317-870-5610
FAX Number: 317-870-5608

Trade Name:
BioScanner Triglycerides Test Strips

Common Name: Triglyceride test system

Panel: Clinical Chemistry 75

Product Code: CDT

Device Classification: Class I

Intended Use
The BioScanner Triglycerides test strips are intended to measure triglyceride in whole blood. (OTC use)

Device Description
Triglycerides are hydrolyzed by lipoprotein lipase to glycerol and fatty acid. Glycerol is phosphorylated by glycerol kinase in the presence of adenosine triphosphate (ATP) forming glycerol-3-phosphate and adenosine-5-diphosphate (ADP). The glycerol-3-phosphate is oxidized by glycerophosphate oxidase to dihydroxyacetone phosphate and hydrogen peroxide. In the presence of peroxide, peroxidase catalyzes the coupling of 4-AAP (4-aminoantipyrine) with an N,N-disubstituted aniline to form a quinoneimine dye.

Predicate Device Information

STATEMENT OF SUBSTANTIAL EQUIVALENCE

Polymer Technology Systems, Inc., intends to introduce into commercial distribution the BioScanner Triglycerides Test Strips for the quantitative determination of Triglyceride in human whole blood. The BioScanner Triglycerides Test Strips are substantially equivalent to the predicate device noted below.

Name:	Triglyceride (GPO-Trinder) Reagent
Device Company:	Sigma
510(k) Number:	K870012

Similarities and Differences (Predicate and BioScanner Triglycerides)

Similarities

- Both systems determine total Triglyceride concentrations in blood.
- Both use a photometer to convert the intensity of color produced in a colorimetric chemical reaction into a triglyceride result.
- Both reagents are similar in their composition in that both use a Trinder reaction to develop the colored end product. The color of the end product is measured and converted into triglyceride concentration and reported in mg/dL

Differences

1. The color development media.

- The BioScanner Triglycerides Test Strips develop color on a dry membrane.
- The predicate device is a wet chemistry. The color of a solution is read.

2. The method of red blood cell separation:

- The predicate method does not separate the serum from the red blood cells. The whole blood must be centrifuged to separate the red blood cells.
- The BioScanner Triglycerides test strip separates the red blood cells, allowing the developed color to be read on the reaction area of the membrane.

3. The calibration method.

- The predicate method requires the running of a calibrator with each run.
- The BioScanner Triglycerides Test Strips contain a lot specific EEPROM memory chip in the same package with the strips. The EEPROM memory chip has the curve information programmed into it based on a multipoint curve that is established for the lot. The user inserts this chip into the instrument with each new lot of test strips. This chip is programmed with information that ensures that the correct lot of strips is used with the chip. If the memory chip and strip lot number do not match, the user will get an error message that keeps the user from running the test until the strip and memory chip are matched.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Margo Enright
Manager of Clinical Affairs
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, Indiana 46268

Re: K000586
Trade Name: BioScanner Triglycerides Test Strips
Regulatory Class: I reserved
Product Code: JGY
Dated: May 25, 2000
Received: June 1, 2000

Dear Ms. Enright:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Center for Devices and Radiological Health

510(k) Number (if known): K000586

Device Name: **BioScanner Triglycerides Test Strips**

Indications for Use:

The BioScanner Triglycerides test strips are intended to be used by professionals and consumers to measure triglyceride in whole blood for use in the diagnosis and treatment of diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000586

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

Home Use ✓